

## **REMARKS**

The amendment appearing above and these explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Applicant responds to the outstanding Action by centered headings that correspond to the centered headings employed by the Office, to ensure full response on the merits to each finding of the Office.

### ***Claim Rejections - 35 U.S.C. § 112, second paragraph***

Applicant acknowledges the quotation of 35 U.S.C. § 112, second paragraph.

Claims 7-10 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In light of the aforementioned amendment(s) and remarks, reconsideration and withdrawal of these grounds of rejection is requested because the newly amended claim(s) now places the application in condition for allowance.

Applicant agrees with the Office that the removal of the URINE LUCK™ (trademark) and elects to change it with the term "adulterant with oxidative activity" as stated clearly in the specification.

Claim 1 has now been changed using the term from the specification "is then pipetted into a single, discrete cuvette" to overcome the rejection of the claim being confusing as suggested by the Examiner.

Claims 8-10 have had the term "can be" removed per the Examiners helpful suggestions.

For the above reasons the application is now in condition for allowance.

### **Double Patenting**

Since the Examiner has required the Applicant to restrict the application to one of several inventions, statute 35 USC 121 overcomes this rejection in favor of the applicant. The statute 35 USC 121 states that if the Applicant files on the non-elected invention(s) after a requirement for restriction, the Applicant can do so with immunity. In addition the use of the Applicant's art of record that is not allowable and nor is it legally defensible. This does not take in the fact that none of the inventions of the Applicants have any bearing on this case and in fact are on completely different subject matters. The difference between the different art of the Inventor is distinctly different and as stated by the Examiner not identical. Again, this is moot because of the provisional position currently.

Claims 7-10 stand as provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of co-pending Applications.

The co-pending Applications cannot serve as a reference against the present application since this application claims CIP (continuation-in-part) status from same co-pending application. The present application, therefore, has the same effective filing date for the elements that Applications teaches or suggests.

Applicant is therefore entitled to the effective filing date of the parent application under 35 U.S.C. §120 since the subject matter now claimed has support under 35 U.S.C. §112 in the parent application. (*See In re Scheiber*, 587 F.2d 62, 199 USPQ 782, 784-85 (CCPA 1978).

Accordingly, the grounds for the provisional rejection simply do not exist under these facts. Applicant respectfully requests the Office remove this ground of rejection and solicits a notice of allowance

***Claim Rejections - 35 U.S.C. § 112, second paragraph and 35 U.S.C. § 103***

Rejection to newly amended claim(s) as being unpatentable over Anne et al (US 6,503,726) in view of Yamashita et al (US 4,158,545) should be reversed because Anne does not teach applicant's limitations as claimed, i.e., no reference by Anne for peroxidase detection as required by Anne? Why the rejection? Therefore, Annes fails the first step of inquiry with respect to a 35 U.S.C. § 102 rejection anticipation reference. See *In re Spada*, 15 USPQ 2d 1655, 1656 (CAFC 1990) where the Court of Appeals For the Federal circuit stated, "Rejection for anticipation or lack of novelty requires, as the first step in the inquiry, that all elements of the elements of the claimed invention be described in a single reference." In addition, the Court stated, "Further, the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it." The device of Smith "**new principle of operation**" in that include the use of a device with different activation means activate the oxidative active compound. Never taught by Anne or any other prior art. The art of Yamashita had absolutely no relative bearing in this or any other action. The Applicant can not even understand the reach that it takes to even suggest Yamashita. Again this is not legally defensible. Not that this argument is allowable, but does the Examiner understand how many patents are allowed on new and novel formulas for "autoanalyzers" on a daily basis?

The applicants invention solves a different problem than the reference, and such differences are cited in the new and amended claims, such as no requirement for a peroxidase, etc.. See *In re Wright*, 6 USPQ 2d 1959 (1988). Since the Examiner's argument does not support a rejection of the newly amended claims under 35

U.S.C. 102, and because the invention of Smith recites numerous novel physical features that would clear any § 102 rejections the decision to reject the claims based on 35 U.S.C. § 102 should be reversed.

Again, rejection to newly amended claim(s) as being anticipated by Anne under 35 U.S.C. § 102 should be reversed because Anne does not teach applicant's limitations as claimed and therefore, Anne fails the first step of inquiry with respect to a 35 U.S.C. § 102 rejection anticipation reference. See *In re Spada*, 15 USPQ 2d 1655, 1656 (CAFC 1990) where the Court of Appeals For the Federal circuit stated, "Rejection for anticipation or lack of novelty requires, as the first step in the inquiry, that all elements of the elements of the claimed invention be described in a single reference." In addition, the Court stated, "Further, the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it."

As the Appellant and other courts have cited, hindsight view of prior art is not allowable. As the Courts have stated, "It is impermissible to use the claimed invention as an instruction manual to "template" or piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that one cannot use hindsight construction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention." in *re Fritch supra*, 1784.

Thus the applicant submits that the present invention clearly recites novel physical subject matter which distinguishes over any possible use of Anne in view of Yamashita.

**The Novel Physical features of the newly amended claim(s) Produce New And Unexpected Results And Hence Are Unobvious And Patentable Over The Reference Under § 102.**

It is impermissible to use hindsight reconstruction of an invention to support a rejection under 35 U.S.C. 103 is improper as clearly set forth by the Court of Appeals For the Federal Circuit in *In re Fritch*, 23 USPQ 2d 1780 at 1783-1784 (CAFC 1992) where it is stated, "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination" ..... "Here, the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This Court has previously stated that '[o]ne

cannot use hindsight reconstruction to pick and choose among isolated disclosures of the prior art to deprecate the claimed invention'."

In line with these decisions, recently the Board stated in Ex parte Levengood, 28 U.S.P.Q.2d 1300 (P.T.O.B.A.&I. 1993):

"In order to establish a *prima facie* case of the obviousness, it is necessary for the examiner to present *evidence*, preferable in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art *would have been led* to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention. ...That which is within the capabilities of one skilled in the art is not synonymous with obviousness. ... That one can *reconstruct* and/or explain the theoretical mechanism of an invention by mean of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed invention.... Our reviewing courts have often advised the Patent and Trademark Office that it can satisfy the burden of establishing a *prima facie* case of obviousness only by showing some objective teaching in either prior art, or knowledge generally available to one of ordinary skill in the art, that 'would lead' that individual 'to combine the relevant teachings of the references.' ... Accordingly, an examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the *motivating force* which would impel one skilled in the art to do what the *applicant has done*."

**The Novel Physical Features Of New and Amended Claim(s) Produce New And Unexpected Results And Hence Are Unobvious And Patentable Over The References Under § 102.**

Without waiving objection as to whether the subject matter of the instant application falls within the unpredictable arts; In re Angstadt<sup>1</sup> is an example of a chemical case involving unpredictable reactions. In Angstadt, the application was initially rejected as non-enabling. The invention related to a process that produced various oxidation products. The application included the discovery that certain metals could be used

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<sup>1</sup> In re Angstadt, 537 F.2d 498, 190 USPQ 214 (C.C.P.A. 1976).

as catalysts to provide production yields at a higher rate. The Examiner rejected the application as non-enabling since the disclosure did not establish how, or which, operative catalysts could be determined to perform the claimed process.

The CCPA reversed the rejection on appeal. Although the CCPA acknowledged that the specification did not disclose every catalyst that would work, it nevertheless held that even in the unpredictable sciences that the specification need not disclose every example or species covered by a claim. Specifically, the CCPA noted:

To require such a complete disclosure would apparently necessitate a patent application or applications with “thousands” of examples or the disclosure of “thousands” of catalysts. ... More importantly, such a requirement would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments. This would tend to discourage inventors from filing patent applications in an unpredictable area since the patent claims would have to be limited to those embodiments which are expressly disclosed. A potential infringer could readily avoid “literal infringement” of such claims by merely finding another analogous catalyst complex which could be used in “forming hydroperoxides.”<sup>2</sup>

Angstadt is clearly analogous to the current situation. Applicant has disclosed numerous compounds that can be used in formulating the current invention. Compiling a list of every compound which may be capable of producing a negative ion solution, and conducting experiments thereon, would place an undue burden on the applicant. Accordingly, it is requested that the rejection on these grounds be withdrawn.

Claims 7-10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Anne in view of Yamashita. The obvious needs to be stated that Anne and Yamashita do not mention anywhere the detection of oxidative active compound and require the use of peroxidase therefore making their art at best remotely related. It has been previously stated that the assessment of oxidative active compounds has nothing to do with the measurement of a oxidase and can be easily proven through and with science. In contrast the device(s) of the Smith invention employs completely different methodologies for the detection of Urine Luck. The method is one step.

In view of Anne and Yamashita the applicant has not nor would claim the use of peroxidase as requirement for the measurement. Mainly because it would not work for the measurement of oxidatively active compounds

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<sup>2</sup> *Id.* at 218

**because peroxidase is an oxidant in itself.** The applicant fails to find in Anne and Yamashita or any references to the novel combination of buffers, indicators and methods as taught by Smith for the detection of Urine Luck.

The Examiner should reverse the rejection of claims 7-10 under 35 U.S.C. § 103(a) as being unpatentable over Anne in view of Yamashita. Because applicant's claims 7-10 recite novel physical features (i.e., it clears § 102). The novel physical distinctions of claims 1 – 2 are unobvious under § 103(a) for the following reasons. The present device produces **unexpected results** due to the inherent design and capability differences between the Smith and the cited prior art. The prior art of Anne does not mention the detection of oxidative compounds because the art of Anne has oxidatively active compounds in the actual reagent. When the present and past devices are juxtapose the results produced are unexpected. The present device is a single step method for the analysis of Urine Luck in urine or other fluids effectively allowing **superior** results with reference to time, cost, and accuracy and ability to do the basic claim which is the detection of Urine Luck without the use of peroxidase, etc. The present device **omits** certain and critical **elements** of the Anne in view of Yamashita device(s). The present art by not including these elements of the prior art is in fact more capable of producing a more **clinically significant** result for the presence of oxidatively active compounds in urine or other fluids therefore producing a **superior** functional device. The prior art of Anne in view of Yamashita do not explain any of the present arts novel features. Anne in view of Yamashita fail to teach or mention in any of their specifications or claims the important step of the detection of oxidatively active compounds. The Examiner has not presented a convincing line of reasoning as to why the claimed subject matter as a whole, including its differences over the prior art, would have been obvious. Anne in view of Yamashita do not teach the present art. The applicant's invention **solves a different problem**, detection of oxidatively active compounds without the use of the prior mentioned restrictions and limitation of Anne in view of Yamashita.

As the Appellant and other courts have cited, hindsight view of prior art is not allowable. As the Courts have stated, "It is impermissible to use the claimed invention as an instruction manual to "template" or piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that one cannot use hindsight construction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention." in re Fritch supra, 1784.

Thus the applicant submits that their invention clearly recites novel physical subject matter which distinguishes over any possible use of Anne in view Yamashita.

**The Newly Amended Novel Physical features of Claims 7-10 Produce New And Unexpected Results And Hence Are Unobvious And Patentable Over The Reference Under § 103.**

Again, Such hindsight reconstruction of an invention to support a rejection under 35 U.S.C. 103 is improper as clearly set forth by the Court of Appeals For the Federal Circuit in *In re Fritch*, 23 USPQ 2d 1780 at 1783-1784 (CAFC 1992) where it is stated, "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination" ..... "Here, the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This Court has previously stated that '[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures of the prior art to deprecate the claimed invention'."

For these reasons, the Examiner's rejection of claims 7-10 under 35 U.S.C. § 103 should be reversed.

Again, the Examiner's rejection of amended claims 7-10 as obvious within the meaning of 35 U.S.C. § 103 over Anne in view of Yamashita should be reversed.

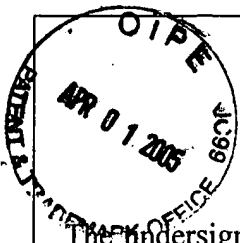
"It is wrong to use the patent in suit [here the patent application] as a guide through the maze of prior art references, combining the right references in the right way to achieve the result of the claims in suit [here the claims pending]. Monday morning quarterbacking is quite improper when resolving the question of nonobviousness in a court of law [here the PTO]."

In line with these decisions, recently the Board stated in Ex parte Levengood, 28 U.S.P.Q.2d 1300 (P.T.O.B.A.&I. 1993):

"In order to establish a *prima facie* case of the obviousness, it is necessary for the examiner to present *evidence*, preferable in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art *would have been led* to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention. ...That which is within the capabilities of one skilled in the art is not synonymous with obviousness.

... That one can *reconstruct* and/or explain the theoretical mechanism of an invention by mean of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed invention.... Our reviewing courts have often advised the Patent and Trademark Office that it can satisfy the burden of establishing a *prima facie* case of obviousness only by showing some objective teaching in either prior art, or knowledge generally available to one of ordinary skill in the art, that 'would lead' that individual 'to combine the relevant teachings of the references.' ... Accordingly, an examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the *motivating force* which would impel one skilled in the art to do what the *applicant has done*."

**The Novel Physical Features Of Amended Claims 7-10 Produce New And Unexpected Results And Hence Are Unobvious And Patentable Over The References Under § 103.**



### Request Under MPEP § 707.07 (j)

The undersigned, a pro-se applicant, respectfully requests that if the Examiner finds patentable subject matter disclosed in this application, but feels that the Applicant's present claim is not entirely suitable, the Examiner draft one or more allowable claims for applicant as a request under MPEP § 707.07 (j)

#### **Conclusion**

Entry of a Notice of Allowance is solicited. If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claim in condition for allowance, a telephone call to the undersigned at (828) 650-0407 is requested.

Very respectfully,

Jack V. Smith

By: 

Dated: March 1<sup>st</sup>, 2005

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### CERTIFICATE OF MAILING (37 C.F.R. 1.8(a))

I HEREBY CERTIFY that this Amendment A, including Amendments to the Specification, Amendments to the Claims, Proposal for Amendments to the Drawings, and Remarks are being Express Mailed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on April 1<sup>st</sup>, 2004.

Express Mail Tracking #: EU757850202US  
Date: April 1<sup>st</sup>, 2004

  
Jack V. Smith